REMARKS

Claims 2-19 are pending. In the Office Action mailed January 5, 2010, the Examiner maintained the rejection of Claim 17 under 35 U.S.C. §102(b); Claims 14-16, 18, and 19 under 35 U.S.C. §103(a); and Claims 2-13 under 35 U.S.C. §103(a). The Examiner also maintained the provisional rejection of Claims 2-19 on the ground of nonstatutory obviousness-type double patenting.

Applicant respectfully requests consideration and allowance of all pending claims in view of the remarks set forth below.

I. Rejection of claim 17 under 35 USC § 102(b)

The Examiner maintained the rejection of claim 17 under 35 U.S.C. §102(b) as being anticipated by Epshtein RU Patent No. 2104006 (RU '006). The Examiner states that Applicant's arguments filed 6/7/2010 have been fully considered but they are not persuasive. The Examiner states that

> Ephstein [*sic*] discloses a method of combining potentiated morphine with the habitual morphine dose to enhance effectiveness of treating withdrawal symptoms (English abstract). It is taught that the potentiated morphine is prepared by successive dilutions according to homeopathic procedure (English language abstract), and that the combination of diluted morphine and habitual amount of morphine is provided during periods of intoxication as well as withdrawal (English abstract).

The Examiner thus concludes that the RU '006 reference discloses a method of enhancing the activity of morphine by combinations of a habitual (therapeutic) amount of morphine with successive homeopathic dilutions of morphine, and therefore, the RU '006 reference anticipates claim 17.

Applicant disagrees.

To anticipate a claim, a reference must disclose either explicitly or inherently, each element of the claim "as set forth in the claim." *Verdegaal Bros. v. Union Oil Co. of Cal.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131.

Claim 17 recites as follows:

> 17. A method of enhancing the activity of an active pharmaceutical substance, wherein said active pharmaceutical substance is morphine, upon administration to a subject suffering from a condition or disorder treatable by said active pharmaceutical substance, said method comprising combining a therapeutic dose of said active pharmaceutical substance with a homeopathically activated form of said active pharmaceutical substance.

Applicant discovered that when a therapeutic dose of an active pharmaceutical substance is combined with a homeopathic dose, the combination results in a potentiation of the pharmacological activity of the compound and/or reduction in the undesired side effects. (See specification page 2, last paragraph and page 3, last paragraph).

It is respectfully submitted to the examiners attention that RU '006 plainly does not disclose a normal therapeutic dose of morphine together with homeopathically activated form morphine, let alone its enhancement. The English abstract, which the examiner cites, describes "administration of potentiated morphine" with "habitual narcotic obtained by homeopathic procedure." (English abstract) (emphasis added). In other words, RU '006 discloses administration of a mixture of two homeopathic forms of a narcotic.

Furthermore, attached herewith is the certification of Edward D. Pergament, a registered United States patent attorney, who is fluent in Russian. He reviewed the entire Russian text of RU '006 and has certified that the description and the examples do not disclose a combination of homeopathically activated form of morphine with non-homeopathically activated form of any other substance.

The undersigned urges that the English abstract on its face is *ipso facto* evidence of lack of disclosure of the combination claimed in claim 17 of the present application. For this reason, the undersigned does not submit a translation of RU '006, which would plainly clarify the issue. However, if the Examiner remains unconvinced, the Examiner is respectfully requested to call the undersigned and a certified translation will be submitted.

In conclusion, RU '006 does not disclose each element as set forth in claim 17, either explicitly or inherently. Accordingly, withdrawal of the anticipation rejection of claim 17 is respectfully requested.

II. Rejection of claims 14-16, 18 and 19 under 35 USC § 103(a)

The Examiner maintained the rejection of Claims 14-16, 18, and 19 under 35 U.S.C. §103(a) as being unpatentable over RU '006 as applied to claim 17 above, and further in view of Epshtein et al., RU Patent No. 2099052 (RU '052). The Examiner states that RU '052 teaches a method of treating withdrawal symptoms associated with alcohol abuse comprising administration of ethanol which has been diluted by homeopathic methods (English abstract). The Examiner concludes that it would have been *prima facie* obvious to enhance the activity of ethanol by administering a combination of ethanol with a homeopathic dilution of ethanol, because RU '006 teaches that this method is effective for enhancing the activity of morphine.

Applicant disagrees.

To establish a *prima facie* case of obviousness, three basic criteria must be met. See MPEP 2143.02; *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). First, there must be some teaching, suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, or some "objective reason" within the meaning of *KSR Int'l v. Teleflex, Inc.* 127 S. Ct. 1727 (2007), to modify the reference or to combine teachings of the prior art to achieve the claimed invention. Second, there must be a reasonable expectation of success. Finally, while the prior art reference (or references when combined) need not explicitly teach or suggest all the claim limitations, the Examiner must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. Unless all of the three criteria are met, a conclusion of obviousness cannot be reached. MPEP §2141.02.

The teaching, suggestion or motivation test has been modified by *KSR Int'l v. Teleflex, Inc.*

127 S. Ct. 1727, 1741 (2007). However, to support obviousness, *KSR* still requires a showing that "there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l v. Teleflex, Inc.* 127 S. Ct. 1727, 1741 (2007).

Claim 14 is directed to a method of enhancing the activity of ethanol comprising administration of a therapeutic dose of ethanol together with a homeopathically activated form of ethanol. Dependent claims 15-16 and 18-19 are drawn to combining the homeopathic and therapeutic dosages of morphine or ethanol prior to administration, and to the dilution ratio of the homeopathically activated form to the active pharmaceutical substance as being is from 1:1 to 1:100.

First, as discussed above, RU '006 plainly does not teach a combination of a therapeutic dose of morphine with a homeopathically activated form of morphine. Instead, RU '006 discloses administration of homeopathic dilutions of morphine together with homeopathic dilutions of another narcotic, that is, a mixture of two homeopathic forms. RU '052 discloses potentiated ethanol obtained by homeopathic method. Neither of the cited references suggests or provides any reason to modify a therapeutic dose of ethanol in the manner of the claimed invention. Thus, the cited references alone or in combination, simply do not teach, suggest or provide any reason to enhance the activity of ethanol in the manner of the claimed invention.

As set forth above, *KSR* continues to require that the prior art provide a reason for the modification in the direction of the invention. The prior art could not have provided the requisite reason because the very reason for the modification is the essence of the present discovery. Thus, one skilled in the art would not have any reason, in view of the cited art, to modify a therapeutic dose of ethanol in the direction of the claimed invention.

Second, The Examiner did not set forth art that provides the requisite "reasonable expectation of success." Neither the cited references, nor the art, at the time the present application was filed, provide one skilled in the art with any expectation of obtaining the results provided in the claimed invention; namely, that the homeopathically activated form of ethanol will modify the properties of the therapeutic dose of ethanol. The specification shows that

administration of the combination of claim 14 is surprisingly more potent than therapeutic dose of ethanol alone or homeopathically activated dilutions of ethanol alone, (see Example 6, page 6 of the specification), establishing that the treatment with homeopathic dilution significantly modifies the properties of a therapeutic dose of ethanol. None of the cited art suggests the surprising result that the administration of a therapeutic dose of an active pharmaceutical substance in combination with a homeopathically activated form of the active pharmaceutical substance would enhance the activity of the active pharmaceutical substance. Thus, one skilled in the art would not have had a reasonable expectation of success.

Third, the Examiner has not set forth prior art that teaches or suggest all elements of the claims. As stated above, the RU '006 reference does not disclose combining a therapeutic dose of morphine with a homeopathically activated form of morphine. RU '052 fails to overcome the deficiency of RU '006. Even if combined, the homeopathic dilutions of ethanol as disclosed in RU '052, using the combination disclosed in RU '006 would fail to include all the elements recited in claim 14, namely, a method of enhancing the activity of ethanol by combining a therapeutic dose of ethanol with a homeopathically activated form of ethanol. Therefore, the combined references fail to disclose, teach or suggest each and every limitation of claim 14.

Given that the cited art do not teach or suggest each and every limitation of claim 14, one or ordinary skill in the art would not arrive at the claimed limitations of dependent claims 15-16 and 18-19.

In conclusion, Applicant asserts that the Examiner has failed to meet the criteria required to support a *prima facie* case of unpatentability. Accordingly, withdrawal of the obviousness rejection of claim 14 and dependent claims 15-16 is respectfully requested. Claims 18 and 19 depend from claim 17 and withdrawal of the obviousness rejection for claims 18 and 19 is also respectfully requested.

III. Rejection of claims 2-13 under 35 U.S.C. §103(a)

The Examiner maintained the rejection of claims 2-13 under 35 U.S.C. §103(a) as being

unpatentable over RU '006, in view of RU '052, as applied to claims 14-16, 18, and 19 above, and further in view of Epshtein et al., PCT/RU01/00239 (PCT '239), and Epshtein et al., PCT/RUO2/00369 (US Patent No. 7,572,441 (US '441")).

The Examiner states that the US '636 publication teaches that compounds such as phenazepam, diazepam, and hydrocortisone are active pharmaceutical agents used for the treatment of various medical conditions and US '441 teaches that cyclophosphamide is an agent which is used for medicinal purposes. The Examiner concludes that it would have been *prima facie* obvious for one of ordinary skill in the art, at the time of the invention, to enhance the activity of pharmaceutical agents such as phenazepam, diazepam, hydrocortisone and cyclophosphamide by the methodology of the combined teachings of the RU '006 and RU '052 because the RU '006 and the RU '052 patents teach a homeopathic method of enhancing the activity of morphine and ethanol, which are also used pharmaceutically. Thus, it would have been obvious that this methodology could also be applied to other pharmaceutical active agents, such as phenazepam, diazepam, hydrocortisone and cyclophosphamide.

Applicant disagrees.

As stated above, to establish a *prima facie* case of obviousness, three basic criteria must be met. See MPEP 2143.02; *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006).

Claims 2, 5, 8 and 11 are drawn to a method of enhancing the activity individually of phenazepam, diazepam, hydrocortisone, and cyclophosphamide, upon administration to an individual suffering from a condition treatable by each active substance, the method comprising combining a therapeutic dose of the active pharmaceutical substance and a homeopathically activated form of the same active pharmaceutical substance. Dependent claims 3-4, 6-7, 9-10 and 12-13 are drawn to the homeopathically activated form prepared by a dilution of 1:1 to 1:100 of active substance to carrier, and that the combination of the dosages is performed prior to administration.

First, the deficiencies of the RU '006 and RU '052 references as concerns claims 14-16, 18, and 19 of the instant application were discussed above.

Second, The Examiner did not set forth art that provides the requisite "reasonable expectation of success." None the cited references, nor the art at the time the present application was filed, provide one skilled in the art with any expectation of obtaining the results provided in the claimed invention; namely, that the homeopathically activated form will modify the properties of the therapeutic dose of an active pharmaceutical agent. Furthermore, even if RU '006 would teach the combination as described by the Examiner, enhancement of activity of one pharmaceutical substance does not necessarily leads to a similar conclusion for another. The specification shows that administration of the combination as claimed in claims 2, 5, 8 and 11 is surprisingly more potent than pharmaceutical substance alone or homeopathically activated dilutions of alone, (see Example 1-2 and 4-5, pages 2-3 and 5-6 of the specification), establishing that the treatment with homeopathic dilution significantly modifies the properties of a therapeutic dose of phenazepam, diazepam, hydrocortisone and cyclophosphamide. The cited references alone or in combination, simply do not teach, suggest or provide any reason to enhance the activity of phenazepam, diazepam, hydrocortisone or cyclophosphamide in the manner of the claimed invention. Thus, one skilled in the art would not have had a reasonable expectation of success.

Third, the Examiner has not set forth prior art that teaches or suggest all limitations of the claim. The cited art alone or in combination does not teach or suggest the combination of claims 2, 5, 8 and 11. As stated above, RU '006 does not disclose combining a therapeutic dose of morphine with a homeopathically activated form of morphine. RU '006 teaches administration of a mixture of two homeopathic forms of a narcotic. RU '052, PCT '239 and PCT '639 all fail to overcome the deficiency of RU '006. Even if combined, the combination of two homeopathic forms of a narcotic as taught by RU '006, using the homeopathic dilutions as disclosed in RU '052 and the compounds disclosed in PCT '239 and PCT '639 would fail to include all the elements recited in claims 2, 5, 8 and 11, namely, a method of enhancing the activity of a pharmaceutical substance by combining a therapeutic dose of the pharmaceutical substance with a homeopathically activated form of the same pharmaceutical substance. Thus, the art cited by the

Examiner does not disclose, teach or suggest all limitations of claims 2, 5, 8 and 11.

Given that the cited art do not teach or suggest each and every limitation of claims 2, 5, 8 and 11, one or ordinary skill in the art would not arrive at the claimed limitations of dependent claims 3-4, 6-7, 9-10 and 12-13.

In conclusion, Applicant asserts that the Examiner has failed to meet the criteria required to support a *prima facie* case of unpatentability. Accordingly, withdrawal of the obviousness rejection of claims 2-13 is respectfully requested.

IV. Provisional Rejections of claims 2-19

The Examiner maintained the rejection of claims 2-19 of the present application over claims 17 and 19-21 of co-pending and co-assigned application No. 09/117,838. Applicant will provide an appropriate Terminal Disclaimer in the present or the cited co-assigned applications at the point in prosecution when no other rejection shall remain.

The applicants therefore respectfully request reconsideration and allowance in view of the above remarks and amendments. The Examiner is authorized to deduct additional fees believed due from our Deposit Account No. 50-4711.

Respectfully submitted,

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